

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

MARICAL, INC., et al.,)	
)	
Plaintiffs)	
)	
v.)	1:14-cv-00366-JDL
)	
COOKE AQUACULTURE, INC., et al.,)	
)	
Defendants)	

**DECISION AND ORDER ON PLAINTIFFS’ MOTION FOR
RECONSIDERATION AND REQUEST FOR CLARIFICATION**

On July 31, 2017, the Court granted Defendants’ Motion for Leave to Amend Their Answer (Motion, ECF No. 214), to permit Defendants to add an affirmative defense and supplement their counterclaim to allege that the four patents-in-suit are unenforceable under the doctrines of inequitable conduct and infectious unenforceability. (Decision and Order, ECF No. 282.) In support of their motion, Defendants stipulated they would “limit the inequitable conduct claims to those ‘representative’ claims in the litigation, and claim 46 of the ‘792 patent.”¹

The matter is before the Court on Plaintiffs’ Motion for Reconsideration and Request for Clarification. (ECF No. 285.) The Court grants in part the motion to the extent Plaintiff seeks clarification.

¹ June 30, 2017, Letter of Michael McGraw, counsel for Defendants.

BACKGROUND

As recited in the Decision and Order, on March 24, 2002, a patent examiner with the United States Patent Office (PTO) issued an office action rejecting all pending claims under the judicially created doctrine of nonstatutory double patenting, citing prior patent number 6,337,391, and explained that “the claims if allowed, would improperly extend the ‘right to exclude’ already granted in the [‘391] patent.” (Proposed Am. Ans. ¶ 16; *see also* ECF No. 214-2.) Subsequently, Plaintiffs overcame the office action, and secured the patents-in-suit, by explaining that the patents differed from the ‘391 Patent because the newly claimed methods involved a “specially made feed” containing NaCl and “at least one PolyValent Cation Sensing Receptor (PVCR) Modulator (e.g., an amino acid),” which were teachings not disclosed in the ‘391 Patent. (ECF No. 214-4.)

In its Decision and Order, the Court explained that Defendants alleged facts with sufficient particularity to support a plausible claim that Plaintiffs represented to the PTO that the patented processes involved the use of “specially made” feed containing an amount of NaCl between about 1% and 10% by weight, or between about 10,000 mg/kg and 100,000 mg/kg, and tryptophan in an amount ranging between 0.1% and 1%, or between 1gm/kg and 10gm/kg,² and that the representation was inequitable because Plaintiffs failed to disclose the material fact that prior art fish feed would meet both limitations.

² For reference, Patent ‘792 states, “the methods also involve adding feed having between about 1% and about 10% NaCl by weight and tryptophan in an amount between about 1 gm/kg and about 10 gm/kg to the freshwater and transferring the pre-adult anadromous fish to seawater.” (Patent ‘792, col. 2, ll. 23 – 24.)

In particular, in support of their motion to amend, Defendants referenced Clarke 6+6 Freshwater Feed, a feed marketed specifically for use during the smoltification process that contained more than 1% added NaCl; and Nutrient Requirements of Fish, published through the National Research Council in 1993 (a/k/a NRC 1993), which disclosed a tryptophan requirement of 0.2% of dry weight for juvenile Chinook salmon. The Court determined that the information could support the plausible inference that the aquaculture industry already had available a prior art feed within the scope of the “specially made feed” described in the patents-in-suit, which patents the PTO issued after Plaintiffs cited the “specially made” character of the feed taught in the patents. The Court found the tryptophan specification particularly relevant to the motion to amend because it appeared that Plaintiffs did not include in the patent applications an adequate prior art reference to dietary tryptophan requirements for salmon. (Decision and Order at 14 – 16.)³

Through their motion for reconsideration and request for clarification, Plaintiffs argue (1) that the finding that Nutritional Requirements of Fish is a material, non-cumulative reference was in error because the patent applications disclosed the reference, “The effect of dietary tryptophan level on growth and metabolism of rainbow trout (*Salmo gairneri*),” (Walton, et al.) Brit. J. Nutrition 51, 279-2987 (1984), which reference was

³ In relation to NaCl content, Defendants have identified a 1983 Zaugg reference (Proposed Am. Ans. ¶¶ 105 – 108), which taught “the inclusion of additional NaCl at 7 to 8% (dry weight) to the diets of all chinook salmon for 4 to 6 weeks prior to release or transfer to seawater,” and a 1991 soviet patent application that taught a fish feed formulation containing sodium chloride between 1 and 12 percent by weight, to “increase the survivability of Atlantic salmon smolt through adaptation to ocean water.” (ECF No. 215-8, PageID # 7860 – 61.) Plaintiffs’ patent applications included references to the Zaugg article. (PageID ## 8260, 8283, 8305, 8328.)

identified in Plaintiffs’ opposition to the motion to amend⁴; (2) that the Decision and Order is unclear because it approves the proposed amended answer without restriction, even though the Court did not find that Plaintiffs omitted a material fact concerning the use of sodium chloride in prior art feed; and (3) that the allegations in the proposed amended answer are not consistent with Defendants’ representation that they would limit the new affirmative defense and counterclaims to the representative claims and claim 46 of the ‘792 patent.

DISCUSSION

To be entitled to relief on their motion for reconsideration, Plaintiffs must demonstrate (1) the availability of new evidence not previously available, (2) an intervening change in controlling law, or (3) the need to correct a clear error of law or to prevent manifest injustice. *Int’l Ass’n of Machinists & Aerospace Workers v. Verso Corp.*, 121 F. Supp. 3d 201, 217 (D. Me. 2015). However, even if Plaintiffs cannot meet this standard, interlocutory orders remain open pending final judgment and the Court therefore has “wide discretion” to revisit prior interlocutory rulings. *Mumme v. U.S. Dep’t of Labor*, 150 F. Supp. 2d 162, 165 (D. Me. 2001); *see also Geffon v. Micrion Corp.*, 249 F.3d 29, 38 (1st Cir. 2001).

Plaintiffs’ contention that reconsideration is warranted because the Court erred in concluding that Defendants adequately alleged inequitable conduct is unpersuasive. The Court nevertheless will clarify the Decision and Order as explained below.

⁴ See ECF No. 224 at 4, 5, 17.

A. Materiality of Withheld Reference

“Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. This judge-made doctrine evolved from a trio of Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). Through a claim of inequitable conduct, a patent infringement defendant asserts that the patentee obtained the patent-in-suit by making material misrepresentations to the PTO or by taking measures to suppress evidence that, if disclosed, would have prevented issuance of a patent. *Id.* at 1285 – 87. “Inequitable conduct occurs when a patentee breaches his or her duty to the PTO of candor, good faith, and honesty.” *U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345, 1352 (Fed. Cir. 2016) (quoting *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1186 (Fed. Cir. 2006), and citing 37 C.F.R. § 1.56(a) (2015) (explaining that a party appearing before the PTO has “a duty to disclose ... all information known to that individual to be material to patentability”)).

For a nondisclosure to meet the materiality standard that applies to a claim of inequitable conduct, the nondisclosure must be the “but for” cause for issuance of the patent. *Therasense*, 649 F.3d at 1291. Nondisclosure of prior art meets this standard “if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” *Id.* A patentee, however, does not commit inequitable conduct by withholding a reference if the patent examiner in fact considered the reference, *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991), *overruled on other grounds by Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009), or if the allegedly withheld

reference would have been less relevant than other information already before the PTO, *Larson Mfg. Co. of S. Dakota v. Aluminart Prod. Ltd.*, 559 F.3d 1317, 1327 (Fed. Cir. 2009).

In the Decision and Order, the Court focused its analysis primarily on the alleged non-disclosure that the Court believed could plausibly support an inequitable conduct claim.⁵ The Court, therefore, assessed the alleged materiality of the Nutritional Requirements of Fish reference published through the National Resource Council in 1993 (NRC 1993), which reference included information concerning the tryptophan content of salmon feed, and which reference did not appear to be rendered immaterial by other prior art disclosed in the patent applications.⁶

For NRC 1993 to be immaterial, it must be “merely cumulative to, or less relevant than, information already considered by the examiner.” *Larson Mfg.*, 559 F.3d at 1327. Information is cumulative if it teaches no more than what a reasonable examiner would consider to be taught by the prior art already of record before the PTO. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1574 – 75 (Fed. Cir. 1997).

Dr. William Harris, the lead inventor of the patents-in-suit, testified that he did not recall whether he disclosed nutritional guidelines to the PTO, even though he discussed

⁵ The Court did not specifically address each alleged non-disclosure. For instance, because the patent applications included the Zaugg reference, the Court concluded, based on *Scripps*, that Defendants’ allegations regarding the Zaugg 1983 references did not constitute and were not evidence of a material nondisclosure. Furthermore, the disclosure of the Zaugg references demonstrated that Defendants’ contention that the alleged nondisclosure of prior art regarding the NaCl content of salmon feed would not support an inequitable conduct claim.

⁶ Also material, Defendants have argued, is a 1988 article entitled Effects of Food Containing Betaine/Amino Acid Additive on the Osmotic Adaptation of Young Atlantic Salmon, *Salmo salar* L. (Virtanen, et al., ECF No. 215-9.) Plaintiffs did not disclose the article in their patents.

them with his lawyers. (*Id.* ¶ 60.) According to Dr. Harris, the other inventors, who also knew all prior art feeds contained tryptophan, similarly failed to disclose the information to the PTO. (*Id.* ¶ 61.) Plaintiffs maintain that if they disclosed other prior art to the PTO, then NRC 1993 would be cumulative and the nondisclosure of NRC 1993 would necessarily be immaterial to the PTO's decision to issue the patents. Plaintiffs argue that their disclosure of the Walton reference renders NRC 1993 cumulative.

The Walton reference is a 1984 article regarding the impact of dietary tryptophan on the development of rainbow trout. The article contains the following reference to salmon: "The quantitative requirement appears to vary with species, being 2 g/kg diet for chinook salmon (*Oncorhynchus tshawytscha*) (Halver, 1965)." Based on their disclosure of the Walton reference, Plaintiffs argue no reasonable finder of fact could find that the failure to disclose NRC 1993 was material to the PTO's decision as to patentability. In other words, Plaintiffs contend that Defendants' proposed amendment would be futile.

NRC 1993 ("Nutritional Requirements of Fish"), unlike the Walton reference, provides a source to determine the nutritional requirements of a number of fish species, including salmon. The publication provides tables that reflect the "amino acid requirements" of various fish, including amino acids as a percentage of dry diet. The tables specify 0.2 percent tryptophan for juvenile chinook salmon and for juvenile coho salmon. (ECF No. 215-4, PageID # 7823, 7826.) Walton, on the other hand, purports to address specifically the nutritional requirements of rainbow trout. While a mention of dietary requirements for chinook salmon is found in the article, the article's title and substance focus on the dietary tryptophan requirements for rainbow trout, and its authors purport to

determine the dietary requirement of 2.5g/kg tryptophan for rainbow trout. (Walton, ECF No. 285-2.) By comparison, disclosure of NRC 1993 would have provided the examiner with a prior art reference containing data for multiple fish, including salmon species. In addition, NRC 1993 supports the inference that commercially available feed used in salmon aquaculture would in fact meet the tryptophan specifications found in the patents.

Given the different focus of the publications, while Plaintiffs could prevail on their claim that the NRC 1993 reference would have been cumulative, a finder of fact⁷ could plausibly find the Nutritional Requirements of Fish non-cumulative. Information is cumulative if it teaches no more than what a reasonable examiner would consider to be taught by the prior art already of record before the PTO. *Regents of the Univ. of Cal.*, 119 F.3d at 1574 – 75. Cumulativeness incorporates relevance considerations. Accordingly, given its focus on rainbow trout, the finder of fact could conclude that the Walton reference is “less relevant” than the withheld NRC 1993/Nutritional Requirements of Fish reference. *Larson Mfg.*, 559 F.3d at 1327. The Court, therefore, cannot conclude that a proposed amendment to assert an inequitable conduct claim would be futile.

B. Scope of Pleadings

Plaintiffs argue that even if the motion to amend is granted, Defendants’ proposed amended answer includes many more allegations than are necessary to assert the

⁷ The defense/counterclaim of inequitable conduct presents a matter within the Court’s equity jurisdiction. Consequently, it is generally determined by the court. *See Rothmann v. Target Corp.*, 556 F.3d 1310, 1322 – 23 (Fed. Cir. 2009). A trial court may exercise its discretion to conduct a hearing on inequitable conduct prior to the jury trial on infringement and other invalidity claims, though that is not required. *Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1372 (Fed. Cir. 2006).

inequitable conduct and infectious unenforceability defenses and counterclaims. To clarify, the Court expects the amended answer to reflect the scope of the amendment permitted and Defendants' stipulated limitation of their contention.

1. Stipulated limitation on the scope of the pleadings

Defendants stipulated that their inequitable conduct counterclaims are limited to the representative claims and claim 46 of the '792 patent. (Defendants' Opposition to Plaintiffs' Motion for Reconsideration at 8, ECF No. 287-1.) The stipulation is binding. *Morales Feliciano v. Rullan*, 303 F.3d 1, 8 (1st Cir. 2002) ("A party's stipulations are binding on that party and may not be contradicted by him at trial or on appeal."). Defendants' amended answer should be in accord with their stipulation.

2. Attributing inequitable conduct to specific actors

Plaintiffs contend the Decision and Order fails to specify whether the allegations would support a finding that anyone other than Dr. Harris was involved in the alleged inequitable conduct. To the extent Plaintiffs maintain that the proposed amendment or the Court's order lacks sufficient specificity, Plaintiffs' argument is unavailing. Defendants have identified Dr. Harris, Plaintiffs' agent, who was involved in the application process and had knowledge of the withheld reference. Together with their allegations of intent, which can be alleged "generally," Fed. R. Civ. P. 9(b), the pleadings are sufficiently particularized to state the inequitable conduct defense and counterclaims.

3. Unnecessary supplemental allegations

Plaintiffs object to the scope of the amended answer and counterclaims because the revised pleading includes allegations, in particular with respect to the prior art, that did not

inform the Court's good cause analysis. Defendants' persuasive good cause argument was supported by the inequitable conduct defense and counterclaims based on Dr. Harris's deposition testimony. In granting the motion to amend, the Court expects Defendants' amended answer to be consistent with claims based on this good cause argument.

CONCLUSION

Based on the foregoing analysis, the Court grants in part Plaintiffs' Motion for Reconsideration and Request for Clarification. Defendants shall file an amended answer in accord with this Decision and Order.

NOTICE

Any objections to this Decision and Order shall be filed in accordance with Federal Rule of Civil Procedure 72.

/s/ John C. Nivison
U.S. Magistrate Judge

Dated this 15th day of November, 2017.